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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,113

11/01/2005

Shinji Nakade

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EXAMINER

RICCI, CRAIG D

ART UNIT

PAPER NUMBER

1628

NOTIFICATION DATE

DELIVERY MODE

03/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

Office Action Summary	Application No. 10/519,113	Applicant(s) NAKADE ET AL.	
	Examiner CRAIG RICCI	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10, 20, 22, 24, 25, 27, 29, 30, 44, 46, 47, 49, 51, 52, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11 and 44 is/are rejected.
- 7) ☒ Claim(s) 22, 24, 25, 27, 29, 30, 46, 47, 49, 51 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/18/2009, 1/05/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

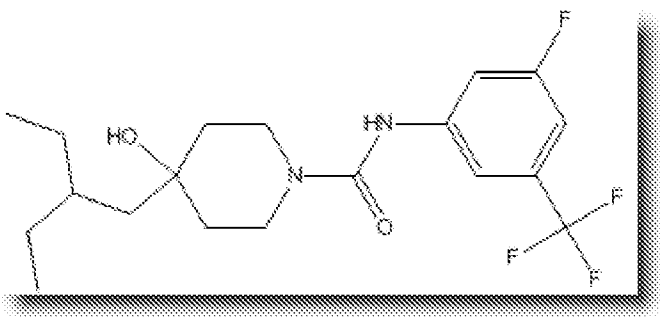
1. The amendments filed 12/01/2009 were entered.

Response to Arguments

2. Applicants' arguments, filed 12/01/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

3. As discussed in the previous Action mailed on 9/01/2009, Applicant's election **without** traverse of the following compound species is acknowledged:



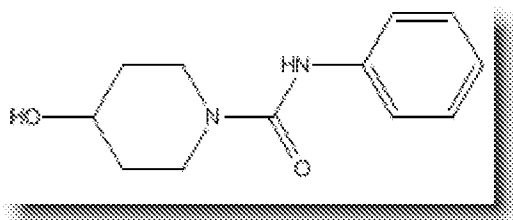
Applicant indicates the structure represents 4-(2-ethylbutyl)-N-(5-fluoro-3-(trifluoromethyl)phenyl)-4-hydroxy-1-piperidinecarboxamide and not 4-(2-ethylbutyl)-N-(3-fluoro-5-(trifluoromethyl)phenyl)-4-hydroxy-1-piperidinecarboxamide as elected. It appears as though the compound structure above may be named either way, although it is actually the same as Applicant's elected species. Nevertheless, Applicant is requested to clarify the election by providing the chemical structure of the elected species.

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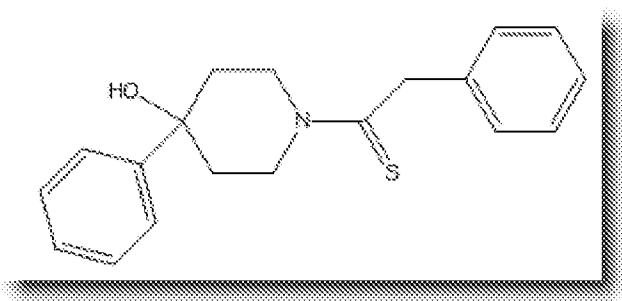
4. The elected species reads on current claims 10, 20, 22, 24-25, 27, 29, 30, 44, 46-47, 49 and 51-52. Claims 1-3 and 61-62 remain withdrawn.

Claim Objections

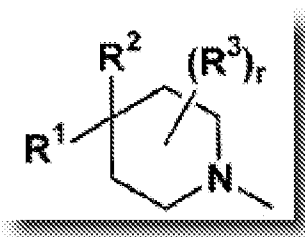
5. In the previous Action it was noted that the elected species was searched and was deemed free of the prior art. Accordingly, the search was expanded as called for under current Office Markush practice - a compound by compound search - to include a single additional species.



That species was . Applicant has overcome the rejection based on said species by amending the claims. Accordingly, the search has again been expanded as called for under current Office Markush practice - a compound by compound search - to include a single additional species. That species is



wherein (in formula (I)) A is



wherein **R¹** is a substituent (i.e., phenyl (see Specification Page 16 for

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a definition of “substituent” of ring A), R^2 is hydroxyl; R^3 is absent (i.e. r is 0); X is a single bond; Y is -CS-; Z is -NH-; and B is phenyl. The above species reads on instant claims 10, 20 and 44. A rejection as to those claims follows.

6. Claims 22, 24-25, 27, 29, 30, 46-47, 49 and 51-52 are objected to as depending from a rejected claim.

7. Claim 10 is also objected to. Claim 10 recites that R_2 represents hydroxyl or C1-6 alkoky. It is believed alkoky is a misspelling and should read alkoxy. Alkoxy is also misspelled regarding Z in claim 10.

Claim Rejections - 35 USC § 102

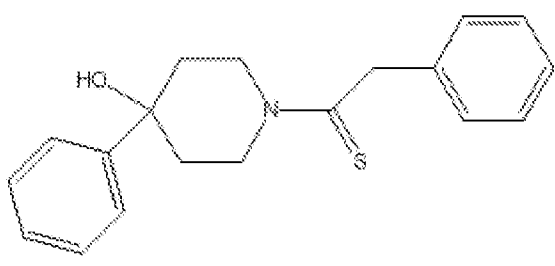
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

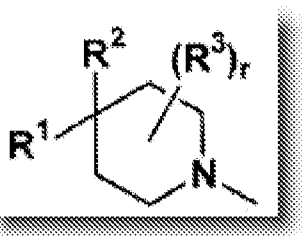
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

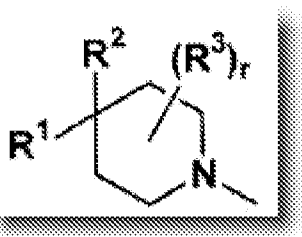
9. **Claims 10-11 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by *Agrawal et al* (Indian Journal of Pharmacy 39(6):139-140, 1977) as evidenced by the attached STN Search Report (Accession Number 1978:130817).**

10. As amended, instant claim 10 is drawn to a compound represented by formula (I) which



encompasses the following compound species



wherein A is  wherein **R**¹ is a substituent (i.e., phenyl (see Specification Page 16 for a definition of “substituent” of ring A), **R**² is hydroxyl; **R**³ is absent (i.e. **r** is 0); **X** is a single bond; **Y** is -CS-; **Z** is -NH-; and **B** is phenyl. The above species reads on claims 10-11 and 44.

11. Support for the amendments can be found at Page 4, Lines 3-15 of the Specification and Claim 17 as originally filed.

12. As evidenced by the attached STN Report (**Accession Number 1978:130817**) *Agrawal et al* teach the above compound species (**CAS RN 65846-22-2**). Accordingly, claims 10-11 and 44 are anticipated.

Conclusion

The new ground(s) of rejection presented in this Office action are necessitated by Applicant's amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan "Paddy" Sreenivasan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

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/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642